

FORM PTO-1449
(REV. 7-80)

NOV 03 2004

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.:
200.1113CON2SERIAL NO.:
10/665,735

LIST OF PRIOR ART CITED BY APPLICANT

(Use several sheets if necessary)

APPLICANT(S):
Philip J. Palermo et al.FILING DATE:
September 18, 2003GROUP:
1614

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
KW	AA	4 5 8 7 1 1 8	05/06/1986	Hsiao	424	459	
	AB						
	AC						
	AD						
	AE						
	AF						
	AG						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
							YES NO
W	AH	04 0 5 2 3 4 6	06/24/04	WO (A1)	A61K	9/62	
W	AI	0 5 4 8 4 4 8	09/06/2000	EP (B1)	A61K	9/50	abstract
	AJ						
	AK						
	AL						

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	AM	
	AN	
	AO	
	AP	
	AQ	
	AR	
	AS	

EXAMINER

Ken Wood

DATE CONSIDERED

5-4-05

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FORM PTO-1449 (REV. 7-99)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: 200.1113CON2		SERIAL NO.: 10/665,735	
LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)				APPLICANT(S): Philip J. PALERMO et al.			
				FILING DATE: September 18, 2003		GROUP: 1614	
U.S. PATENT DOCUMENTS							
*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
16	AA	2 7 7 0 5 6 9	11/56	Fromherz et al.	167	65	
	AB	3 1 3 3 1 3 2	05/12/64	Loeb, et al.	264	49	
	AC	3 1 7 3 8 7 6	03/16/65	Zobrist	252	137	
	AD	3 2 7 6 5 8 6	10/04/66	Rosaen	210	90	
	AE	3 3 3 2 9 5 0	7/67	Blumberg et al.	260	285	
	AF	9 4 8 3 6 5 7	2/70	Lewenstein et al.	424	260	
	AG	3 6 7 8 5 5 7	7/72	Lachman et al.	424	260	
	AH	3 7 7 3 9 5 5	11/73	Pachter et al.	424	260	
	AI	3 8 7 5 5 5 5	4/75	Pachter et al.	424	260	
FOREIGN PATENT DOCUMENTS							
	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
16	AJ	8 3 0 3 1 5 7	9/83	WO	A61K	9/22	
	AK	9 0 0 4 9 5 5	05/17/1990	WO	A61K	31/485	
	AL	9 8 0 8 8 2 8	3/94	WO	A61K	31/46	
	AM	9 5 0 3 8 0 4	2/95	WO	A61K	31/485	
	AN	9 6 0 2 2 5 1	2/96	WO	A61K	31/485	
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)							
16	AO	Foss, J.F., et al. Abstract, "Prevention of Apomorphine- or Cisplatin- induced emesis in the dog by combination of Methylnaltrexone and Morphine", Cancer Chemother Pharmacol (1998); 42(4):287-91.					
	AP	Yuan et al., "Efficacy of Orally Administered Methylnaltrexone in Decreasing Subjective Effects After Intravenous Morphine", Drug and Alcohol Dependence (1998); 52:161-165.					
	AQ	Gan et al., "Opioid-Sparing Effects of a Low-Dose Infusion of Naloxone in Patient-Administered Morphine Sulfate," Anesthesiology (1997), 87(5):1075-1080.					
	AR	Shen et al., "Ultra-Low Doses of Naltrexone or Etorphine Increase Morphine's Antinociceptive Potency and Attenuate Tolerance/Dependence in Mice," Brain Research (1997), 757:176-190.					
	AS	Yuan et al., "The Safety and Efficacy of Oral Methylnaltrexone in Preventing Morphine-Induced Delay in Oral-Cecal Transit Time", Clinical Trials and Therapeutics (1997), 61:467-475.					
	AT	Mendelson J., et al, "Buprenorphine and Naloxone Interactions in Opiate Dependent Volunteers," Clin. Phar. Ther. (1996), 60:105-114.					
	AU	Walsh et al., "Effects of Naltrexone on Response to Intravenous Cocain, Hydromorphone and their Combination in Humans," (1996).					
EXAMINER 16				DATE CONSIDERED 5-4-05			
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RW	BA	3	9	1	6	8	8	9	11/04/1975	Russell	128	145.8		
	BB	3	9	6	5	2	5	6	06/22/1976	Leslie	424	22		
	BC	3	9	6	6	9	4	0	6/76	Pachter et al.	424	260		
	BD	4	1	7	6	1	8	6	11/79	Goldberg	424	260		
RW	BE	4	2	3	7	1	4	0	12/02/1980	Dudzinski	424	260		
FOREIGN PATENT DOCUMENTS														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
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RW	BF	9	7	3	3	5	6	6	9/97	WO	A61K	9/20		
	BG	9	8	3	5	6	7	9	8/98	WO	A61K	31/485		
	BH	9	9	3	2	1	2	0	7/99	WO	A61K	31/485		
	BI	0	0	0	1	3	7	7	01/13/2000	WO	A61K	31/00		
RW	BJ	8	7	0	1	2	8	2	03/12/1987	WO	A61K	31/485		
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
RW	BK	Chih-Cheng Chien, et al., "Sigma Antagonists Potentiate Opioid Analgesia in Rats", Neuroscience Letters 190 (1995), 137-139.												
	BL	Crain et al., "Ultra-Low Concentrations of Naloxone Selectively Antagonize Excitatory Effects of Morphine on Sensory Neurons, Thereby Increasing Its Antinociceptive Potency and Attenuating Tolerance/Dependence During Chronic Cotreatment," Proc. Natl. Acad. Sci. USA (1995) 92:10540-10544.												
	BN	Hanson, Analgesic, Antipyretic and Anti-Inflammatory Drugs in Remington's Science and Practice of Pharmacy (1995), 2:1207.												
	BO	Talwin NX, Physician's Desk Reference 48 th Ed. (1994) Montvale, NJ 2120-2121.												
	BP	Foss et al., "Dose related Antagonism of the Emetic Effect of Morphine by Methylnaltrexone in Dogs", J. Clin Pharmacol (1993), 33:747-751												
	BQ	Holmes et al., "Inhibiting Spinal Dynorphin A Component Enhances Intrathecal Morphine Antinociception in Mice", Anesth. Analg. (1993), 77:1166-73.												
RW	BR	Miakowski et al., "Inhibition of Spinal Opioid Analgesia by Supraspinal Administration of Selective Opioid Antagonists", Brain Research (1992), 30:263-274.												
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16								4 2 8 5 9 4 7	08/25/1981	Ayer, et al.	427	3			
								4 3 6 6 3 1 0	12/28/1982	Leslie	536	56			
								4 4 0 1 6 7 2	8/83	Portoghese et al.	424	260			
								4 4 4 3 4 2 4	04/17/1984	Oshlack et al.	424	22			
								4 4 5 4 4 7 0	5/84	Ganti	424	260			
								4 4 5 7 9 3 3	7/84	Gordon et al.	424	260			
								4 4 6 4 3 7 8	8/84	Hussain et al.	424	260			
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		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION		
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16		CH	0	1	3	2	4	8	0	05/10/2001	WO (A2)	A61K	31/485		
		CI	0	4	6	4	0	8	0	09/20/2001	WO (A2)	A61K	31/00		
		CJ	0	1	3	7	7	8	5	05/31/2001	WO (A2)	A61K			
		CK	0	1	5	2	8	5	1	07/26/2001	WO (A1)	A61K	31/485		
		CL	0	1	8	5	2	5	7	11/15/2001	WO (A2)	A61P			
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)															
16	CM	Weinhold et al., "Buprenorphine Alone and in Combination with Naltrexone in Non-Dependent Humans," Drug and Alcohol Dependence (1992), 30:263-274.													
	CN	Cappel et al., "Enhancement of Naloxone Induced Analgesia by Pretreatment with Morphine" Pharma. Bioch. & Behav. (1989), 34:425-427.													
	CO	Vaccarino et al., "Analgesia Produced by Normal Doses of Opioid Antagonists Alone and in Combination with Morphine", Pain (1989), 36:103-109.													
	CP	Gonzalez et al., "Naltrexone: A Review of its Pharmacodynamic and Pharmacokinetic Properties and Therapeutic Efficacy in the Management of Opioid Dependence," Drugs (1988), 35:192-213.													
	CM	Sunshine, et al., "Analgesic Efficacy of Pentazocine Versus a Pentazocine-Naloxone Combination Following Oral Administration," Clin. J. Pain (1988), 4:35-40.													
	CR	Wang et al., "Crossover and Parallel Study of Oral Analgesics," J. Clin. Pharmacol (1981), 21:162-168.													
	CS	Translation of German patent application DE 43 25 465													
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Kc	DA	4	5	7	3	9	9	5	8/86	Chen et al.	604	896			
	DB	4	5	8	2	6	3	5	4/86	Lewis et al.	514	282			
	DC	4	6	0	9	3	7	5	8/86	Pasternak	514	282			
	DD	4	5	6	1	4	9	2	4/87	Lewis et al.	514	282			
	DE	4	7	1	9	2	4	5	1/88	Goldberg	514	282			
	DF	4	7	3	0	0	0	8	3/88	Portoghese et al.	546	45			
Kc	DG	4	7	0	0	0	6	5	7/88	Rzeszotarski et al.	514	282			
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	DI	0	9	1	3	1	5	2	6/99	EP	A61K	31/485			
	DJ	9	9	4	7	4	4	8	4/95	EP	A61K	31/485			
	DK	0	3	5	2	3	6	1	1/90	EP	A61K	31/485			
Kc	DL	0	2	6	5	2	8	2	12/86	EP	A61K	9/22			
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)															
Kc	DM	Alvarez-Fuentes, et al. "Effectiveness of Repeated Administration of a New Ora Naltrexone Controlled-Release System in Morphine Analgesia"; J. Pharm Pharmacol (2001), 53:1201-1205.													
	DN	Alvarez-Fuentes, et al., "Preclinical Study of an Oral Controlled Release Naltrexone Complex in Mice"; J. Pharm Pharmacol (2000), 52:659-663.													
	DO	Archer, Sydney; "Historical Perspective on the Chemistry and Development of Naltrexone"; Naltrexone Research Monograph 28 (1980) p. 3-9.													
	DP	Baum et al., "The Impact of the Addition of Naloxone on the Use and Abuse of Pentazocine"; Public Health Reports (1987) Vol. 102, No. 4 p. 426-429.													
	DQ	Rapaka et al., "Discovery of Novel Opioid Medications"; NIDA Research Monograph 147 (1995) p. 55-83.													
Kc	DR	Bloom et al., "Clinical Studies with Naloxone/Methadone in a Ratio of 1:20"; 5 th National Conference on Methadone Treatment (1973) Vol 2, p. 1342-1349.													
EXAMINER <div style="font-size: 1.5em; margin-top: 10px;">Kc</div>										DATE CONSIDERED <div style="font-size: 1.5em; margin-top: 10px;">5-4-05</div>					
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166	EA	4	7	6	9	3	7	2	9/88	Kreek et al.	514	282		
	EB	4	7	8	5	0	0	0	11/88	Kreek et al.	514	282		
	EC	4	8	0	3	2	0	8	2/89	Pasternak	514	282		
	ED	4	8	0	6	3	4	1	2/89	Chien et al.	424	448		
	EE	4	8	0	6	5	4	3	2/89	Choi	514	464		
	EF	4	8	0	6	5	5	8	2/89	Wuest et al.	514	381		
166	EG	4	8	2	8	8	3	6	05/09/1989	Elger et al.	424	419		
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		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO	
166	EH	0	1	9	3	3	5	5	09/03/1986	EP (A3)	A61K	31/615		
	EI	0	3	1	9	2	4	3	06/07/1989	EP (A1)	A61K	31/485		
	EJ	0	3	1	9	2	4	3	11/07/1990	EP (B1)	A61K	31/485		
	EK	19	6	5	1	5	5	1	6/98	DE	A61K	31/485		
166	EL	29	7	1	9	7	0	4	2/97	DE	A61K	31/485		
OTHER PRIOR ART (including Author, Title, Date, Pertinent Pages, Etc.)														
166	EM	Briscoe et al., "Methoclocinnamox: Time Course of Changes in Alfentanil-Reinforced Rhesus Monkeys"; Psychopharmacology (2000) 148:393-399.												
	EN	Abstract of Bromm, et al., "A Sensitive Method to Evaluate Effects of Analgesics in Man"; Meth and Find Exptl Clin Pharmacol 5 (8) (1983) p. 545-551.												
	EO	Bullingham et al., "Clinical Pharmacokinetics of Narcotic Agonist-Antagonist Drugs"; Clinical Pharm (1983) 8: 332-343.												
	EP	Calimlim, et al. "Effect of Naloxone on the Analgesic Activity of Methadone in a 1:10 Oral Combination"; Clin Pharmacol and Ther (1974) Vol. 15; No. 6 pp.556-564.												
	EQ	Caruso et al., "Methadone and Naloxone in Combination (Naldone®) for the Treatment of Heroin Addicts"; Bristol Laboratories, pp.1336-1341F.												
	ER	Cherny, Nathan I., "Opioid Analgesics"; Drugs (1996) May;51 (5) pp. 713-737.												
166	ES	Chiang, et al. "Clinical Evaluation of a Naltrexone Sustained-Release Preparation"; Drug and Alcohol Dependence (1985) 16, pp.1-8.												
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KW	FA	4	8	3	4	9	6	5	05/30/1989	Martani et al.	424	488			
	FB	4	8	3	4	9	8	4	05/30/1989	Goldie et al.	424	488			
I	FC	4	8	3	4	9	8	5	05/30/1989	Elger et al.	424	488			
	FD	4	8	4	4	9	0	7	07/04/1989	Elger et al.	424	488			
I	FE	4	8	4	4	9	0	9	07/04/1989	Goldie et al.	424	480			
	FF	4	8	4	4	9	1	0	07/04/1989	Leslie et al.	424	494			
KW	FG	4	8	6	1	5	9	8	8/89	Oshlak et al.	424	468			
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K	FH	4	3	2	5	4	6	5	2/95	DE	A61K	31/485			x
	FI	2	2	2	2	0	3	9	11/72	DE	A61K	27/00			
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	FK	0	0	3	8	6	4	9	07/06/00	WO	A61K	9/00	abstract		
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)															
KW	FL	Chiang et al., "Kinetics of a Naltrexone Sustained-Release Preparation"; Clin Pharmacol Thera (1984) Vol 36 No. 5, pp.704-708.													
	FM	Comer et al., "Depot Naltrexone: Long-lasting Antagonism of the Effects Of Heroin un Humans"; Psychopharmacology (2002) 159, pp.351-360.													
I	FN	Crabtree et al., "Review of Naltrexone, a long-acting Opiate Antagonist"; Clinical Pharmacy, Vol. 3 (1984) pp.273-280.													
	FO	Crain et al., "Antagonists of Excitatory Opioid Receptor Functions Enhance Morphine's Analgesic Potency and Attenuate Opioid Tolerance/dependence liability"; Dept. of Neuroscience, Albert Einstein College of Medicine Pain 82 (1999) pp.1-11.													
I	FP	Crain et al., "Antagonists of Excitatory Opioid Receptor Functions Enhance Morphine's Analgesic Potency and Attenuate Opioid Tolerance/dependence liability"; Dept. of Neuroscience, Albert Einstein College of Medicine Pain 84 (2000) pp.121-131.													
	FQ	Fink et al., "naloxone in Heroin Dependence"; Clin Pharm and Thera. Vol 9, No. 5:pp.568-577.													
KW	FR	Fishman et al., "Disposition of Naloxone-7,8- ³ H in Normal & Narcotic Dependent Men"; J. Pharm. And Exper. Thera (1973) Vol 10 No. 2:pp.575-580.													
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160	GA	4 8 6 1 7 8 1	8/89	Goldberg	514	282	
	GB	4 8 6 7 9 8 5	09/19/1989	Heafield et al.	424	461	
	GC	4 8 7 3 0 7 8	10/89	Fishman et al.	412	10	
	GD	4 8 8 2 3 3 5	11/89	Sindair	514	282	
	GE	4 8 6 9 8 6 0	12/89	Rzeszotarski et al.	514	282	
	GF	4 8 3 5 4 2 8	6/90	Lewis	514	282	
160	GG	4 9 4 0 5 8 7	07/10/1990	Jenkins et al.	424	480	
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		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
							YES NO
160	GH	00 1 5 8 4 7 7	8/16/01	WO	A61P		abstract
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)							
160	GI	Fraser, Albert D., et al., "Clinical Toxicology of Drugs Used in the Treatment of Opiate Dependency"; Clinical Toxicology 1 (1990) Vol 10, No. 2; pp.375-386.					
	GJ	Freys et al., "Effects of Tramadol and Tilidine/Naloxone on Oral-Caecal Transit & Pupillary light Reflex"; Arzneim-Forsch/Drug Res. 50(I)(2000)pp. 24-30.					
	GK	Fudala, et al., "Effects of Buprenorphine asnd Naloxone in Morphine-Stabilized Opioid Addicts"; Drug and Alcohol Dependence 50 (1998) pp. 1-8.					
	GL	Fudala et al., "Human Pharmacology and Abuse Potential Of Nalmefene"; Clin Pharm and Thera (1991) Vol 49, 3, pp. 300-306.					
	GM	Gal et al., "Prolonged Blockade of Opioid Effect with Oral Nalmefene"; Clin Pharm and Thera (1986) pp. 537-542.					
	GN	Gerra et al., "Clonidine and Opiate Receptor Antagonists in the Treatment of Heroin Addiction"; J. Substance Abuse Treatment (1995) Vol 12, 1, pp. 35-41.					
160	GO	Ghodse, et al., "Opioid analgesics and Narcotic Antagonists"; Side Effects of Drugs (2000) Annual 23, chpt 8 pp. 96-113.					
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166	HA	4 2 0 0 9 8	04/29/1980	Ayer, et al.	128	260	
	HB	4 9 7 0 7 5	11/13/1990	Oshlak	424	451	
	HC	4 9 8 7 1 3 6	01/22/1991	Kreek et al.	514	282	
	HD	4 9 9 0 3 4 1	02/05/1991	Goldie et al.	424	484	
	HE	5 0 7 1 6 4 6	12/10/1991	Malkowska et al.	424	497	
	HF	5 0 7 5 3 4 1	12/91	Mendelson et al.	514	282	
166	HG	5 9 8 6 0 5 8	2/92	Sinclair et al.	514	282	
FOREIGN PATENT DOCUMENTS							
	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
166	HH	00 1 8 5 1 5 0	11/15/01	WO	A61K	31/00	
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)							
166	HI	Glatt, William, M.D. FACP, "A New Method for Detoxifying Opioid-Dependent Patients"; J. Substance Abuse Treatment (1999) Vol.17, No.3, pp. 193-197					
	HJ	Gold, et al. "Rapid Opioid Detoxification During General Anesthesia"; Anesthesiology (1999) Vol 91, No 6, pp. 1639-1647.					
	HK	Greenwald, et al., "Comparative Clinical Pharmacology of Short-Acting μ Opioids in Drug Abusers"; J. Pharm and Exper Thera (1996) Vol 277, No 3, pp. 1228-1236.					
	HL	Gupta, et al., "Morphine Combined with Doxapram or Naloxone"; Anesthesia (1974) Vol 29, pp. 33-39.					
	HM	Richter et al., "Clinical Investigation on the Development of Dependence during Oral Therapy with Tramadol"; Arzneim-Forsch/Drug Res. 35 (No II)(1985)pp. 1742-1744.					
	HN	Rosen et al., "The effect of Lamotrigine on Naloxone-precipitated Opiate withdrawal"; Drug and Alcohol Dependence (1998) Vol 52, pp. 173-176.					
166	HO	Rosen et al., "A Pilot Study of Dextromethorphan in Naloxone-Precipitated Opiate Withdrawal"; European J. of Pharm. (1996) Vol 307, pp. 251-257.					
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LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)						APPLICANT(S): Philip J. PALERMO et al.								
						FILING DATE: September 18, 2003		GROUP: 1614						
U.S. PATENT DOCUMENTS														
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16	IA	5	0	9	1	1	8	9	02/25/1992	Heafield et al.	424	457		
	IB	5	0	9	6	7	1	5	3/92	Sinclair	424	449		
	IC	5	1	0	2	8	8	7	4/92	Goldberg	514	282		
	ID	0	1	6	0	0	2	6	07/03/1979	Ayer, et al.	424	15		
	IE	5	1	4	5	5	3	8	9/92	Granger et al.	424	449		
	IF	5	2	1	5	7	5	8	06/01/1993	Krishnamurthy	424	488		
16	IG	5	2	2	5	4	4	0	7/93	London et al.	514	535		
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16	IH	00	0	6	7	7	3	9	11/16/00	WO	A61K	31/00		
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
16	IJ	Schuh et al., "Buprenorphine, Morphine and Naloxone Effects during Ascending Morphine Maintenance in Humans"; J. Pharm and Exper Thera (1996) Vol 278, 2, pp. 836-846.												
	IK	Schuh et al., "Onset, Magnitude and Duration of Opioid Blockade Produced by Buprenorphine and Naltrexone in Humans"; Psychopharmacology (1999) Vol 145, pp. 162-174.												
	IL	Stevens et al., "Nonspecific Excitatory Effects of Morphine: Reverse-Order Precipitated Withdrawal and Dose-Dose Interactions"; Psychopharmacology (1981) Vol 75, pp. 210-211.												
	IM	Stine et al., "Reduction of Opiate Withdrawal-like Symptoms by Cocaine Abuse during Methadone and Buprenorphine Maintenance"; Am. J. Drug and Alcohol Abuse (1994) Vol 20, 4, pp. 445-458.												
	IN	Stine et al., "Use of Drug Combinations in Treatment of Opioid Withdrawal"; J. Clinical Psych. (1992) Vol 12, No 3, pp. 203-209.												
	IO	Stoller et al., "Effects of buprenorphine/naloxone in opioid-dependent humans" Psychopharmacology (2001) Vol 154, pp. 230-242.												
	IP	Strain et al., "Acute Effects of Buprenorphine, hydromorphone and naloxone in methadone-maintained volunteers"; J. Pharm and Exper Thera (1992) Vol 261, No 3, pp. 985-993.												
	IQ	Strain et al., "Effects of buprenorphine versus buprenorphine/naloxone tablets in non-dependent opioid abusers"; Psychopharmacology (2000) Vol 148, pp. 374-383.												
	IR	Strain et al., "Precipitated Withdrawal by Pentazocine in Methadone-Maintained Volunteers"; J. Pharm and Exper Thera (1993) Vol 267, No 2, pp. 624-634.												
16	IS	Tai, et al., "Naltrexone: An Antagonist Therapy for Heroin Addiction"; NIDA (1997) 5 pages												
EXAMINER 40. 16										DATE CONSIDERED 5-4-05				
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166	JA	5	2	2	6	3	3	1	07/13/1993	Thompson et al.	73	865.9		
	JB	5	2	3	6	7	1	4	8/93	Lee et al.	424	449		
	JC	5	2	5	6	4	6	9	10/93	Askanazi et al.	514	282		
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	JE	5	2	7	3	7	6	3	12/93	Oshlak et al.	424	486		
	JF	5	2	8	6	4	9	3	02/15/1994	Oshlak et al.	424	468		
166	JG	5	3	1	6	7	5	9	10/93	Rose et al.	424	10		
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166	JI	Umbrecht et al., "Naltrexone shortened opioid detoxification with buprenorphine"; Drug and Alcohol Dependence (1999) Vol 56 pp. 181-190												
	JK	Vaccarino et al., "Enogenous Opiates: 1999"; Peptides 21 (2000) pp. 1975-2034.												
	JL	Wang et al., "Inverse Agonists and neutral antagonists at μ opioid receptor (MOR): possible role of basal receptor signaling in narcotic dependence"; J. Neurochemistry (2001) Vol 77, pp. 1590-1600.												
	JM	Way et al., "Responsivity to Naloxone during Morphine Dependence"; Annals New York Academy of Sciences, pp. 252-261.												
	JN	Weinberg et al., "Sublingual absorption of selected opioid analgesics"; Clin Pharm Thera (1988) Vol 44, No 3, pp. 335-342.												
	JO	Wells, et al., "In vivo Pharmacological Characterization of SoRI 9409, a Nonpeptidic Opioid μ -Agonist/ δ -Antagonist that Produces Limited Antinociceptive Tolerance and Attenuates Morphine Physical Dependence"; J. Pharm and Exper Thera (2001) Vol 297, No 2, pp. 597-605												
	JP	Wodak, Alex, "Drug Treatment for Opioid Dependence"; Australian Prescriber (2001) Vol 24, No 1, pp. 4-6.												
	JQ	Wright et al., "Acute physical dependence in Humans; repeated naloxone-precipitated withdrawal after a single-dose of methadone"; Drug and Alcohol Dependence (1991) Vol 27, pp. 139-148.												
166	JR	Zhu et al., "Naltrexone-precipitated morphine withdrawal in infant rat is attenuated by acute administration of NOS inhibitors but not NMDA receptor antagonists"; Psychopharmacology (2000) Vol 150, pp. 325-336.												
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<div style="font-size: 2em; margin-bottom: 10px;">K</div> <div style="font-size: 2em;">F</div>	KA	5 3 1 7 0 2 2	5/94	Borsodi et al.	514	282	
	KB	5 3 2 1 6 1 2	6/94	Mayer et al.	514	25	
	KC	5 3 2 4 3 5 2	06/28/1994	Oshlak et al.	106	153	
	KD	5 3 3 6 6 9 1	08/09/1994	Raffa et al.	514	629	
	KE	5 3 5 2 6 8 0	10/94	Portoghese et al.	514	279	
	KF	5 3 5 2 6 8 3	10/94	Mayer et al.	514	289	
<div style="font-size: 2em;">K</div>	KG	5 3 5 6 4 6 7	10/18/1994	Oshlak et al.	106	153	
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<div style="font-size: 2em;">K</div>	KH	6 1 5 8 4 5 1	08/19/2001	WO (A1)	A61K	31/485	
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)							
<div style="font-size: 2em;">K</div>	KI	Han et al., "Mucocoadhesive buccal disks for novel nalbuphine prodrug controlled delivery; effect of formulation variable on drug release and mucocoadhesive performance"; <i>International J. Pharm</i> (1999) Vol 177, pp. 201-209.					
<div style="font-size: 2em;">K</div>	KJ	Handal et al., "Naloxone"; <i>Annals of Emergency Medicine</i> (1983) Vol 12:7, pp. 438-445.					
<div style="font-size: 2em;">K</div>	KK	Harris et al., "Buprenorphine and Naloxone co-administration in opiate dependent patients stabilized on sublingual buprenorphine"; <i>Drug and Alcohol Dependence</i> (2000) Vol 61, pp. 85-94.					
<div style="font-size: 2em;">K</div>	KL	Hawkes et al., "Effect of enteric-release formulation of naloxone on intestinal transit in volunteers taking codeine"; <i>Aliment Pharm Ther</i> (2001) Vol 15, pp. 625-630.					
<div style="font-size: 2em;">K</div>	KM	Högger et al., "Comparison of tilidine/naloxone, tramadol and bromfenac in experimental pain: a double-blind randomized crossover study in healthy human volunteers"; <i>International J. Clin Pharm and Thera</i> (1999) Vol 37, No 8, pp. 377-385					
<div style="font-size: 2em;">K</div>	KN	Budd, Keith, "Clinical Use of Opioid Antagonists"; <i>Bailliere's Clinical Anesthesiology</i> (1987) Vol 1, No 4, pp. 993-1011.					
<div style="font-size: 2em;">K</div>	KO	Crain et al., "Ultra-low concentrations of naloxone selectively antagonize excitatory effects of morphine on sensory neurons, thereby increasing its antinociceptive potency and attenuating tolerance/dependence					
<div style="font-size: 2em;">K</div>	KP	Howes et al., "The Pharmacology of TR5109, a new Narcotic Agonist/Antagonist Analgesic"; <i>NIDA Research</i> (1979) pp. 99-105.					
<div style="font-size: 2em;">K</div>	KQ	Leeling et al., "Disposition and metabolism of codorphone in the rat, dog, and man"; <i>Drug Metabolism and Disposition</i> (1982) Vol 10, No 6, pp 649-653.					
EXAMINER <div style="font-size: 2em; margin-top: 10px;">KW</div>				DATE CONSIDERED <div style="font-size: 2em; margin-top: 10px;">S-4-05</div>			
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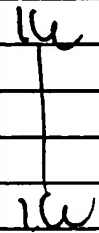








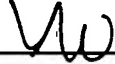
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16								5 3 5 6 9 0 0	10/94	Bihari et al.	514	282	
								5 3 7 6 6 6 2	12/94	Ockert	514	282	
								3 5 4 1 0 0 5	11/17/1970	Strathmann, et al.	210	19	
								5 4 1 1 7 4 5	05/02/1995	Oshlack et al.	424	456	
								5 4 7 6 1 1 2	06/95	Zagon et al.	514	282	
								3 5 4 1 0 0 6	11/17/1970	Bixler, et al.	210	23	
16								5 4 5 7 2 6 4	10/95	Portoghese et al.	546	35	
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16								LH 0 2 8 0 3 5 2	02/03/1998	EP (B1)	A61K	31/485	x
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)													
16	LI	Amass et al., "Efficacy of daily and alternate-day dosing regimens with the combination buprenorphine-naloxone tablet"; Drug and Alcohol Dependence (2000) Vol 58, pp. 143-152.											
	LJ	Hassain et al., "Buccal and oral bioavailability of naloxone and naltrexone in rats"; (1987) Vol 36, pp. 127-130.											
	LK	Jasinski et al., "The human pharmacology and abuse potential of N-allylnoroxymorphone naloxone"; J. Pharm and Exper Thera (1967) Vol 157, No 2, pp. 420-426.											
	LM	Jones et al., "Nalmefene: blockade of intravenous morphine challenge effects in opioid abusing humans"; Drug and Alcohol Dependence (2000) Vol 60, pp. 29-37.											
	LN	Kanof et al., "Clinical Characteristics of Naloxone-Precipitated Withdrawal in Human Opioid-Dependent Subjects"; J Pharma and Exper Thera (1992) Vol 260, No. 1, pp. 355-363.											
	LO	King et al., "Naltrexone Biotransformation and Incidence of Subjective Side Effects: A Preliminary Study"; Alcoholism: Clin and Exper Res (1997) Vol 21, No 5, pp. 906-909.											
	LP	Kogan et al., "Estimation of the Systemic Availability and Other Pharmacokinetic Parameters of Naltrexone in Man after Acute and Chronic Oral Administration"; Res. Comm. In Chem. Path. And Pharm (1977) Vol 18, No. 1, pp 29-34.											
	LQ	Kosten, Thomas R., M.D., "Buprenorphine for Benzodiazepine-Abusing Heroin Addicts"; Amer J of Psychiatry (1994) Vol 1, p 151.											
	LR	Kosten et al., "Opioid antagonist challenges in buprenorphine maintained patients"; Drug and Alcohol Dependence (1990) Vol 25, OO. 73-78.											
16	LS	Kurland et al., "Naloxone and the Narcotic Abuser: A Controlled Study of Partial Blockade"; Inter. J. of the Addictions (1974) Vol 9, No 5, pp. 663-672.											
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	MA	5 4 6 0 8 2 6	10/24/1995	Merrill et al.	424	470		
	MB	5 4 7 2 7 1 2	12/05/1995	Oshlack et al.	424	480		
	MC	5 4 7 2 9 4 3	12/95	Crain et al.	514	12		
	MD	5 4 7 8 5 7 7	12/26/1995	Sackler et al.	424	489		
	ME	5 4 8 6 3 6 2	1/96	Kitchell et al.	424	426		
	MF	5 5 0 0 2 2 7	03/19/1996	Oshlack et al.	424	476		
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						YES	NO	
	MG							
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)								
	MH	Lee et al., "Nalbuphine Coadministered with Morphine Prevents Tolerance and Dependence"; Anesth Analg (1997) Vol 84, pp.810-815						
	MI	Lehman, et al., "Influence of Naloxone on the Postoperative Analgesic and Respiratory effects of Buprenorphine"; Eur. J. Clin Pharm (1988) Vol 34, pp. 343-352.						
	MJ	Levine et al., "Potentiation of Pentazocine Analgesia by Low-dose Naloxone"; J Clin Invest (1988) Vol 82, pp. 1574-1577.						
	MK	Loimer et al., "Combined Naloxone/Methadone Preparations for Opiate Substitution Therapy"; J. of Substance Abuse Treatment (1991) Vol 8, pp. 157-160.						
	ML	Martin et al. "Bioavailability Investigation of a New Tilidine/Naloxone Liquid Formulation Compared to a Reference Formulation"; Arzneim-Forsch./Drug Res. (1999) Vol 49, pp. 599-607.						
	MM	Martin et al., "Demonstration of Tolerance to and Physical Dependence on N-allynmorphine (Nalorphine)"; J. Of Pharm and Exper Thera (1965) Vol 150, No 3. Pp. 437-442.						
	MN	Mendelson et al., "Buprenorphine and naloxone combinations: the effects of three dose ratios in morphine stabilized, opiate-dependent volunteers"; Psychopharmacology (1999) Vol 141, pp. 37-46.						
	MO	Mendelson et al., "Buprenorphine and naloxone Interactions in Methadone Maintenance Patients"; Society of Biological Psychiatry (1997) Vol 41, pp. 1095-1101.						
		MP	Nutt et al., "Methadone-naloxone mixture for use in methadone maintenance programs"; Clin Pharm and Ther. Vol 15, No 2., pp 156-166					
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		5	5	0	8	0	4	3	04/16/1996	Krishnamurthy	424	484	
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OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)													
	NG	Parwatarikar et al., "Methadone-naloxone in combination for the Treatment of Heroin Addicts"; Clin. Pharm and Thera, Vol 14, No. 6, pp 941-948.											
	NH	Parwatarikar et al., "Naloxone-Methadone Combination for the Treatment of Opiate Dependence"; Missouri Institute of Psychiatry, pp. 1350-1354.											
	NI	Pitts et al., "Antinociceptive and Response Rate-Altering Effects of <i>Kappa</i> Opioid Agonists, Spiradoline, Enadoline and U69,593, Alone and in Combination with Opioid Antagonists in Squirrel Monkeys"; J of Pharm and Exper Thera (1994) Vol 271, No 3, pp. 1501-1508.											
	NJ	Preston et al., "Buprenorphine and Naloxone alone and in combination in Opioid-dependant Humans"; Psychopharmacology (1988), Vol 94, pp. 484-490.											
	NK	Preston et al., "Differential Naltrexone Antagonism of Hydromorphone and Pentazocine Effects in Human Volunteers"; J of Pharm and Exper Thera (1993) Vol 264, No 2 pp. 813-823.											
	NL	Preston et al., "Effects of Sublingually given naloxone in Opioid -dependant human volunteers"; Drug and Alcohol Dependence (1990) Vol 25, pp. 27-34.											
	NM	Bigelow et al., "Abuse Liability and Assessment of Buprenorphine-Naloxone Combinations"; Dept of Psychiatry and Behavioral Sciences, The Johns Hopkins University School of Medicine, pp. 145-149.											
	NN	Wikler et al., "N-Allylnormorphine: Effects of single dose and Precipitation of Acute "Abstinence Syndromes" during addiction to morphine, methadone or heroin in man (post addicts)"; N-Allylnormorphine During Narcotic Addiction (1953) pp. 8-20.											
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	OC	5	5	5	2	4	2	2	09/03/1996	Gauthier et al.	514	368	
	OD	5	5	5	8	8	3	8	9/96	Mayer et al.	514	25	
	OE	5	5	7	4	0	5	2	11/96	Rose et al.	514	343	
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												YES	NO
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OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)													
	OG	Zaks et al., "Naloxone Treatment of Opiate Dependence"; JAMA (1971) Vol 215, No 13, pp. 2108-2110.											
	OH	Barton, et al., "Intranasal Administration of Naloxone by Paramedics"; Prehospital Emergency Care (2002) Vol 6, No 1, pp. 54-58.											
	OI	Blachly, Paul, H., M.D., "Naloxone in Opiate Addiction"; Current Psychiatric Therapies (1976) pp. 209-213.											
	OJ	Bashaw et al., "Relative bioavailability of controlled-release oral morphine sulfate during naltrexone blockade"; Inter J of Clin Pharm and Thera (1995) Vol 33, No 9, 524-529.											
	OK	Jasinski, D.R., "Assessment of the Abuse Potential of Morphinelike Drugs (Methods Used in Man)"; Drug Addiction (1977) pp. 197-258.											
	OL	Johnson et al., "Buprenorphine and Naloxone for Heroin Dependence"; Substance Use Disorders (2000) pp. 519-526.											
	OM	Strain et al., "Opioid antagonist effects of dezocine in opioid-dependent humans"; Clin Pharm and Thera (1996) Vol 60, No 2, pp. 206-217.											
	ON	Preston et al., "Abuse liability and studies of opioid agonist-antagonists in humans"; Drug and Alcohol Dependence (1991) vol 28, pp. 49-82.											
	OO	Brennscheidt et al., "Pharmacokinetics of Nortilidine and Naloxone after Administration of Tilidine/Naloxone Solution or Tilidine/Naloxone Sustained Release Tablets"; Arznei-Forsch/Drug Res. (2000) Vol 50, pp. 1015-1022.											
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LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)				APPLICANT(S): Philip J. PALERMO et al.			
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*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
<div style="font-size: 2em; font-family: cursive;">16</div>	PA	5 5 7 8 7 2 5	11/96	Portoghese et al.	546	35	
	PB	5 5 8 0 8 7 6	12/96	Crain et al.	514	282	
	PC	5 5 8 3 3 4 8	12/96	Crain et al.	514	12	
	PD	5 5 9 1 4 5 2	01/04/1997	Miller et al.	424	468	
	PE	5 6 0 1 8 4 5	02/11/1997	Buxton et al.	424	495	
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OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)							
<div style="font-size: 2em; font-family: cursive;">16</div>	PC	Benfey, "Function of Myocardial α -Adrenoceptors"; Life Sciences (1982) vol 31, pp. 101-112.					
	PH	Levine et al., "Potentiation of Pentazocine Analgesia by Low-dose Naloxone"; J of Clin Invest. (1988) Vol 82, pp. 1547-1577.					
	PL	Yoburn et al., "Opioid Antagonist-induced Receptor Upregulation: Effects of Concurrent Agonist Administration"; Brain Research Bulletin (1994), Vol 33, pp. 237-240.					
	PL	Bunzow et al., "Molecular Cloning and Tissue Distribution of a Putative Member of the Rat Opioid Receptor Gene Family that is not a μ , δ , or κ opioid receptor type"; FEBS letters (1994) pp. 284-288.					
	PK	Mollereau et al., "ORL 1, a novel member of the opioid receptor family: Cloning, functional expression and localization"; FEBS letters 341 (1994), pp. 33-38.					
	PL	Wang, et al., "cDNA cloning of an orphan opiate receptor gene family member and its splice variant"; FEBS letters 348 (1994) pp. 75-79.					
<div style="font-size: 2em; font-family: cursive;">16</div>	PM	Suzuki et al., "Morphine conditioned place preference after chronic treatment with naloxone in the rat"; Research Communications in Substance Abuse (1991) vol 12., No 3., pp. 119-131.					
	EXAMINER <div style="font-size: 2em; font-family: cursive;">16</div>			DATE CONSIDERED <div style="font-size: 1.5em; font-family: cursive;">5-4-05</div>			
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	QA	5	6	1	6	6	0	1	4/97	Khanna et al.	514	399		
	QB	5	6	2	2	7	7	2	04/22/1997	Knott et al.	424	494		
	QC	5	6	2	4	9	3	2	4/97	Qin et al.	514	282		
	QD	5	6	3	3	2	5	9	5/97	Qin et al.	514	282		
	QE	5	6	3	9	4	7	6	06/17/1997	Oshlack et al.	424	494		
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	QF													
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	QG	Press Release "International Patent Application to Be Published on Abuse-Resistant Pain Reliever Being Developed by Perdue Pharma"; August 8, 2001.												
	QH	Paronis et al., "Increased Analgesic Potency of Mu Agonists after Continuous Naloxone Infusion in Rats"; J of Pharm Exper Thera (1991), 259 (2), pp. 582-589.												
	QL	Yoburn et al., "Supersensitivity to Opioid Analgesics Following Chronic Opioid Antagonist Treatment: Relationship to Receptor Sensitivity"; Pharmacology Bio Beh (1995) Vol 51 No. 2, pp. 535-539.												
	QJ	Crain et al., "Acute thermal hyperalgesia elicited by low-dose morphine in normal mice is blocked by ultra-low-dose naltrexone, unmasking potent opioid analgesia"; Brain Research (2001) Vol 888, pp. 75-82.												
	QK	Zhang et al., "Down-Regulation of μ -Opioid Receptors in Rat and Monkey Dorsal Root Ganglion Neurons and Spinal Cord After Peripheral Axotomy"; Neuroscience (1998) Vol 82., pp. 223-240.												
	QL	Abdulla et al., "Axotomy reduces the effect of analgesic opioids yet increases the effect of nociceptin on dorsal root ganglion neurons"; J of Neuro Sci (1998) Vol 18, pp 9685-9694.												
	QM	Di Giannuario et al., "Orphanin FQ reduces morphine-induced dopamine release in the nucleus accumbens: a microdialysis study in rats"; Neurosci. Lett (1999) Vol 272 pp. 183-186.												
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	RB	5 6 7 0 1 7 2	09/23/1997	Buxton et al.	424	495			
	RC	5 6 7 2 3 6 0	09/30/1997	Sackler et al.	424	490			
	RD	5 6 8 1 5 8 5	10/28/1997	Oshalck et al.	424	494			
	RE	5 7 6 3 4 5 2	06/09/1998	Miller et al.	514	282			
	RF	5 7 6 7 1 2 5	06/98	Crain et al.	514	282			
	RG	5 7 8 0 4 7 9	07/14/1998	Kim	514	282			
	RH	5 7 6 7 1 2 5	06/16/1988	Crain, et al.	514	282			
	RF	6 0 9 6 7 5 6	08/01/2000	Crain, et al.	514	282			
	RJ	6 1 9 4 3 8 2	02/27/01	Crain, et al.	514	2			
	RK	6 3 6 2 1 9 4	03/26/2002	Crain, et al.	514	285			
	RL	6 3 9 5 7 0 5	05/28/2002	Crain, et al.	514	2			
	RM	20 01 00 06 9 6 7	07/05/2001	Crain, et al.	514	253.04			
	<div style="font-size: 2em;">16</div>	RN	20 01 00 18 4 1 3	08/30/2001	Crain, et al.	514	2		
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<div style="font-size: 2em;">16</div>	RP	Ciccocioppo et al., "Effect of Nociceptin/orphanin FQ on the Rewarding Properties of Morphine"; Eur. J Pharmacol (2000) Vol 404, pp. 153-159.							
<div style="font-size: 2em;">16</div>	RQ	Physician's Desk Reference (2001) see Revia, pp. 1146-1149 and Oxycontin, pp. 2697-2701							
	RR								
	RS								
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	TB	5 8 7 9 7 0 5	03/09/1999	Heafield et al.	424	464			
	TC	5 8 8 0 1 3 2	3/99	Hill	514	282			
	TD	5 8 9 1 4 7 1	04/06/1999	Miller et al.	424	468			
	TE	5 9 0 8 8 4 8	06/01/1999	Miller et al.	514	282			
	TF	5 9 4 2 2 4 1	8/99	Chasin et al.	424	426			
	TG	5 9 5 8 4 5 2	09/28/1999	Oshlack et al.	424	457			
	TH	3 8 4 5 2 7 0	11/05/1974	Theeuwes et al.	128	260			
	TI	4 0 6 3 0 6 4	12/13/1977	Saunders et al.	219	121			
	TJ	4 0 8 8 8 6 4	05/09/1978	Theeuwes et al.	219	121			
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	TL	4 9 5 7 6 8 1	09/18/1990	Klimesch et al.	264	211.23			
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	UC	5	9	6	5	1	6	3	10/12/1999	Miller et al.	424	468		
	UD	5	9	6	8	5	4	7	10/99	Reder et al.	424	449		
	UE	5	9	6	8	5	5	1	10/19/1999	Oshlack et al.	424	456		
	UF	5	9	7	2	9	5	4	10/99	Foss	514	282		
16	UG	5	9	9	8	4	3	4	12/99	Mitch et al.	514	210.16		
	UH	3	1	7	3	8	7	7	03/16/1965	Jackson et al.	252	138		
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	VD	6	0	7	7	5	3	2	06/20/2000	Malkowska et al.	424	457		
	VE	6	0	7	7	5	3	3	06/20/2000	Oshlack et al.	424	461		
	VF	6	1	0	3	2	5	8	08/15/2000	Simon	424	449		
	VG	6	1	0	3	2	6	1	08/15/2000	Chasin et al.	424	459		
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	XD	6 3 3 5 0 3 3	01/01/2002	Oshlack et al.	424	468	
	XE	6 3 7 3 9 5 7	04/23/2002	Kaiko et al.	424	400	
	XF	6 3 8 7 4 0 4	05/14/2002	Oshlack et al.	424	480	
	XG	6 3 9 9 8 9 6	06/04/2002	Miller et al.	424	464	
	XH	6 4 7 5 4 9 4	11/05/2002	Kaiko et al.	424	400	
	XI	6 6 2 7 6 3 5	09/30/2003	Palermo, et al.	514	282	
	XJ	6 7 1 6 4 6 9	04/06/2004	Oshlack, et al.	424	449	
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XL		6 6 9 6 0 6 6	02/24/2004	Kaiko et al.	424	400	
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